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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,499	09/05/2003	Yuan Chang	62681-Z/JPW/AJM/AJD	8346

7590 06/17/2004

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EXAMINER	
SALIMI, ALI REZA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,499	CHANG ET AL.	
	Examiner	Art Unit	
	A R Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/5/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-62,92 and 93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-62,92 and 93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/5/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 48-62, 92-93 are pending.

Raw Sequence Listing have been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

Response to Amendment

The receipt of preliminary amendment of 9/5/2003, is acknowledged. Claims 1-47 have been canceled. Claims 48-62, 92-93 are pending before the examiner.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Please, update the information by including the patent number.

Claim Rejections - 35 USC § 112

Claims 48-62, 92-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 is vague and indefinite, the intended metes and bounds of the polypeptide is not defined. Moreover, intended metes and bounds of the antibody is/are not defined. In addition, the

claim is confusing for recitation of "capable" of this limitation does not set forth positively whether or not the intended antibody actually does "specifically" bind to the protein. In addition, the claim is confusing for recitation of "specifically", this is a relative term, subject to varied interpretation. The claim has been interpreted in light of the specification and since there is no teaching of specificity or capability, or even an antibody the claim is considered to be vague and indefinite. This affects the dependent claims.

Claim 57 is vague and indefinite, the intended metes and bounds of the polypeptide is not defined. This affects the dependent claims.

Claim 92 is vague and indefinite the intended metes and bounds of antibody is/are not defined. Is the intent to claim patient serum antibody? Please clarify? This affects the dependent claims.

Claim Rejections - 35 USC § 101

Claims 48-62, 92-93 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 48-62, 92-93, as written, do not sufficiently distinguish over antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught in the specification. See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-62, 92-93 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant disclosure, the applicants have only disclosed the protein sequence identified as SEQ ID NO: 2 that is directed to LANA2. The art of raising an antibody against a disclosed protein is routine, hence, even though the specification has not taught a specific an antibody or antibodies of any kind it is concluded that antibody(s) against the SEQ ID NO: 2 finds sufficient written description in the original disclosure. However, no other sequences were disclosed, and as a consequence it would be impossible to raise an antibody against undisclosed sequences. In other words raising or detecting antibodies against sequences that lack written description would be rather impossible if the structure of the protein is not defined. The specification does not set forth the metes and bounds of those sequences other than the said sequence, and there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed sequences. Therefore, a written description of the other claimed sequences or antibodies that specifically bound the proteins should be disclosed to overcome this rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would

encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 19 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no

more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 112

Claims 48-62, 92-93 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for forming antibodies against SEQ ID NO: 2, does not reasonably provide enablement for raising antibodies against any and all LANA 2 of HHV-8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Applicants are reminded that the state of the art in this field is considered to be highly unpredictable, even though , the skill in this art is considered to be high. With regard to an unpredictable field, See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). Applicants cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Due to lack of adequate teaching undue experimentation would be required to enable the full scope of the claimed invention. At the onset Office concedes that the art of raising an antibody against a known protein is routine. However, raising antibodies against unknown protein is not routine, and if the structure of the protein is not provided it would be nearly impossible to form a antibody or detect any antibody or diagnose any dieses for that matter. Applicants have taught the SEQ ID NO: 2, and even tough no antibody has been taught forming an antibody against

SEQ ID NO: 2 or detecting SEQ ID NO: 2 is routine, but raising antibodies against an unknown proteins is not routine. The claimed antibodies are formed against specific peptide(s) i.e. SEQ ID NO: 2 there is no teaching about any other polypeptide, Absent adequate teaching one of ordinary skill in the art would be forced into undue experimentation to enable the full scope of the claimed invention. Therefore, according to the state of the art, unpredictability of the field, and lack of adequate teaching by the specification undue experimentation would be required for one of ordinary skill in the art to enable the full scope of the invention. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-62, 92-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Rainbow et al (Journal of Virology, Aug. 1997, Vol. 71, No. 8, pp. 5915-5921).

The broad limitation of the claimed invention is anticipated by the above cited art. Rainbow et al taught antibodies against LANA of HHV-8, and detected serum antibodies against Kaposi's sarcoma (see the abstract, and page 5916, left column, 3rd full paragraph, also see page

5920, 2nd paragraph). The product disclosed in the above cited art appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the teaching of the above cited art anticipates the claimed invention. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 48, 49, 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al (WO 98/04576).

The antibody taught in the above cited reference clearly anticipates the broad limitations of the claimed invention (see claims 14, 17, 18, 19). The product disclosed in the above cited art appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. The antibodies have long range of detestability, and absent side by side comparison, it is determined that the products are the same. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claims 48-62, 92-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al (Virology, April 1999, Vol. 256, pp. 381-392).

Zhu et al taught antibodies against LANA of HHV-8, and detected serum antibodies against Kaposi's sarcoma (see the abstract). They also taught antibody labeling (see page 384, 1st full paragraph), and method of determining disease (see page 389, left column, 1st full

paragraph). The product disclosed in the above cited art appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the teaching of the above cited art anticipates the claimed invention. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 48-62, 92-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Kellam et al (Journal of Virology, June 1999, Vol. 73, No. 6, pp. 5194-5155).

The broad limitation of the claimed invention is anticipated by the above cited art. Kellam et a taught antibodies against LANA of HHV-8, and detected serum antibodies against Kaposi's sarcoma (see the abstract). They also taught antibody labeling (see Figure 1), and method of determining disease (see page 5152, right column, 1st full paragraph, and page 5154, last paragraph). The product disclosed in the above cited art appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the teaching of the above cited art anticipates the claimed invention. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 48-62, 92-93 are rejected under 35 U.S.C. 102(a) as being anticipated by Pierrotti et al (Journal of Clinical Virology, May 2000, Vol. 16, pp. 247-251).

The broad limitation of the claimed invention is anticipated by the above cited art. Pierrotti et a taught antibodies against LANA of HHV-8, and detected serum antibodies against Kaposi's sarcoma (see the abstract). They also taught antibody labeling (see page 384, 1st full paragraph), and method of determining disease (see page 389, left column, 1st full paragraph). The product disclosed in the above cited art appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the teaching of the above cited art anticipates the claimed invention. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 48, 49, 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Haas et al (U.S. 6,319,667 B1).

The antibody taught in the above cited reference clearly anticipates the broad limitations of the claimed invention (see claims). The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. The antibodies have long range of detestability, and absent side by side comparison, it is determined that the products are the same. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A. R. Salimi

6/15/2004